Registration Decision RD2012-07

Pyraclostrobin Seed Treatment

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Registration Decision for BAS 500 F ST

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST, containing the active ingredient pyraclostrobin as a seed treatment, to protect barley, corn and wheat against diseases caused by seed- and soil-borne pathogens.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

The PMRA is also granting full registration for the sale and use of BAS 516 F ST, containing boscalid and pyraclostrobin, to protect canola and canola-quality *Brassica juncea* against diseases caused by seed- and soil-borne pathogens. The registration decision for BAS 516 F ST is presented in Registration Decision RD2011-06, *Boscalid Seed Treatment*.

BAS 500 F Crystalline Technical Fungicide and BAS 500 F ST were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-15, *Pyraclostrobin Seed Treatment*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for BAS 500 F ST and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-15, *Pyraclostrobin Seed*. This decision is consistent with the proposed registration decision stated in PRD2011-15, *Pyraclostrobin Seed Treatment*.

For more details on the information presented in this Registration Decision, please refer to PRD2011-15, *Pyraclostrobin Seed Treatment*, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Pyraclostrobin?

Pyraclostrobin is a strobilurin fungicide that inhibits spore germination, mycelial growth and sporulation on plant surfaces. Pyraclostrobin was first registered in Canada as a broad-spectrum foliar fungicide in 2003 as Headline EC Fungicide and Cabrio EG Fungicide for use on various crops. Additional products have also been registered including Insignia EG Fungicide for use on turf, and Pristine WG Fungicide, which is a combination product containing both pyraclostrobin and boscalid for use on various crops and ornamentals.

Health Considerations

Can Approved Uses of Pyraclostrobin Affect Human Health?

Exposure to pyraclostrobin may occur through diet (food and water), when handling and applying the product or when working in treated areas. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pyraclostrobin products according to label directions.

In rats, pyraclostobin is of low acute oral and dermal toxicity, but is moderately toxic by the inhalation route. It is minimally irritating to the eye and mildly irritating to the skin of rabbits. Pyraclostrobin does not cause an allergic skin reaction in guinea pigs.

The end-use product, BAS 500 F ST, is of slight toxicity to rats via the oral and of low toxicity via the dermal and inhalation routes. It is minimally irritating to the eye and mildly irritating to the skin of rabbits. BAS 500 F ST does not cause an allergic skin reaction in guinea pigs.

Pyraclostrobin did not cause cancer in animals and was not genotoxic. There was also no indication that pyraclostrobin caused damage to the nervous system and there were no effects on reproduction. The first signs of toxicity in animals given daily doses of pyraclostrobin over long periods of time were effects on the gastrointestinal (GI) tract, liver and spleen. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When pyraclostrobin was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, though the effects observed were more severe, indicating that the fetus was more sensitive to pyraclostrobin than the adult animal. Consequently, extra protective measures were applied during the risk assessment to further reduce the allowable level of human exposure to pyraclostrobin.

Occupational Risks From Handling BAS 500 F ST

Occupational risks from handling BAS 500 F ST are not of concern when label directions are followed.

Farmers and custom applicators have potential for exposure to pyraclostrobin during mixing, loading and application as a seed treatment, and during bagging, loading and planting treated seed. The occupational exposure for these use scenarios is not of concern when the products are used according to the label directions.

Residues in Water and Food

Dietary risks from food and water are not of concern

Aggregate dietary intake estimates (food plus water) revealed that the general population and children 1-2 years old, the subpopulation which would ingest the most pyraclostrobin relative to body weight, are expected to be exposed to less than 13% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from pyraclostrobin is not of concern for all segments of the population. There is no evidence that pyraclostrobin is carcinogenic; therefore, a cancer dietary exposure assessment is not required.

A single dose of pyraclostrobin is not likely to cause acute health effects in the general population (including infants and children). The acute aggregate (food and water) dietary intake estimate for females 13-49 years old is less than 64% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

The MRLs for pyraclostrobin in/on canola and mustard (oilseed variety), wheat, barley and corn have been established based on the data generated following foliar application use. The proposed seed treatment use of pyraclostrobin on these crops is not expected to result in residues exceeding their established MRLs.

Environmental Considerations

What Happens When Pyraclostrobin Is Introduced Into the Environment?

Environmental risks are not of concern

Pyraclostrobin is introduced into the environment when it is used as a seed treatment. A limited exposure in soil and water is expected when pyraclostrobin is formulated as a seed treatment. However, birds and mammals may be exposed to this substance if they feed on treated seeds. A risk assessment has indicated that pyraclostrobin does not present a risk to wild mammals and birds.

Value Considerations

What is the value of BAS 500 F ST?

BAS 500 F ST is a seed treatment for corn, wheat and barley proposed to target seed- and soil-borne pathogens.

BAS 500 F ST has broad spectrum activity with protective and curative properties. Seed- and soil-borne pathogens cause diseases that manifest in reduced stands, poor seedling vigour and reduced yield and quality. Seed treatment fungicides increase the likelihood of producing healthy seedlings, which could lead to mature crops that are more tolerant to foliar challenges and improved yield.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of BAS 500 F ST to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing, loading, calibrating, applying, bagging/stacking, cleaning/repairing treatment equipment and handling seed treated with BAS 500 F ST must wear a long-sleeved shirt and long pants, coveralls, chemical-resistant gloves made of any waterproof material and shoes plus socks.

When treating seed in commercial seed treatment facilities, closed transfer including closed mixing, loading, calibrating, and closed treatment equipment must be used. Use of an open transfer system is allowed when treating seed on-farm only.

A closed cab planter is required for planting treated corn seed or for planting more than 8000 kg treated wheat or barley seed per day. All workers outside of a closed cab during planting must wear a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material and shoes plus socks.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-15, *Pyraclostrobin Seed Treatment*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.